AUG - 8 2008

510(k) Summary

Submitted By:

Nathan Simon
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
812.339.2235

14 March 2008

Device:

Trade Name:	MiraFlex™ High Flow Microcatheter
Proposed Classification:	Catheter, Continuous Flush KRA

Indications for Use:

The MiraFlex™ High Flow Microcatheter is designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use.

Predicate Devices:

The MiraFlex™ High Flow Microcatheter is similar in terms of intended use, materials, and technological characteristics to the predicate MiraFlex™ 18 Microcatheter cleared under 510(k) number K060224.

Device Description:

The MiraFlex™ High Flow Microcatheter is an infusion catheter with a hydrophilic coating, designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures. The device is available with a 2.8 French shaft and is available in 100, 110, 135, and 150 cm lengths. The device is supplied sterile and intended for one-time use.

Substantial Equivalence:

The MiraFlex™ High Flow Microcatheter is substantially equivalent to the predicate MiraFlex™ Microcatheter cleared under 510(k) number K060224.

Test Data:

The MiraFlex™ High Flow Microcatheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were:

1. Tensile tests
2. Burst and pressure tests
3. Kink radius and stiffness tests
4. Torque response tests
5. Flow rate tests
6. Embolic particle tests
7. Leakage tests
8. Shelf life tests
9. Biocompatibility tests

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cook Incorporated
c/o Mr. Nathan Simon
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

AUG - 8

Re: K080737
Trade/Device Name: MiraFlex™ High Flow Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II
Product Code: KRA
Dated: July 10, 2008
Received: July 11, 2008

Dear Mr. Simon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K080737

Device Name: MiraFlex™ High Flow Microcatheter

Indications for Use:

The MiraFlex™ High Flow Microcatheter is designed for use in small vessel or superselective anatomy for diagnostic and interventional procedures including neuro, peripheral, or coronary use.

Prescription Use ___X___ OR Over-the-Counter Use

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080737